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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,066	05/07/2001	Bruce A. Kehr	20010427	9510
20277 7590 07/16/2007 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			EXAMINER NAJARIAN, LENA	
			ART UNIT 3626	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/845,066	Applicant(s) KEHR ET AL.	
	Examiner Lena Najarian	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-87 is/are pending in the application.
- 4a) Of the above claim(s) 50-73 and 76-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-49, 74, 75 and 80-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Notice to Applicant

1. This communication is in response to the Request for Continued Examination (RCE) filed 5/3/07. Claims 38-49, 74-75, and 80-87 have been examined.

Response to Amendment

2. The amendment to the claims filed on 5/3/07 does not comply with the requirements of 37 CFR 1.121(c) because previously withdrawn claims 50-73 and 76-79 are now identified as "previously presented."

Also, in response to Applicant's request to obtain copies of provisional applications 60/052,222 and 60/029,862, please see 37 CFR 1.14.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 38-49, 74-75, 80, and 83-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (6,039,688).

(A) Referring to claim 38, Douglas discloses a method for automatically customizing medical protocols, comprising the steps of (col. 2, lines 30-47 of Douglas):

receiving data relating to one or more patients (col. 2, lines 30-41 of

Douglas);

customizing one or more medical protocols based on the received data to derive one or more customized medical protocols (col. 2, lines 30-47 of Douglas);

transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients (Fig. 1 and col. 5, lines 27-53 of Douglas).

(B) Referring to claim 39, Douglas discloses wherein the one or more medical protocols include a medical treatment plan (col. 2, lines 40-44 of Douglas; the Examiner interprets "therapeutic program" to be a form of "medical treatment plan").

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(C) Referring to claim 40, Douglas discloses wherein the data relating to a patient is received from a medical monitoring device associated with the patient, the data including a response to a medical questionnaire (col. 18, lines 6-17 of Douglas).

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Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(D) Referring to claim 41, Douglas discloses wherein the information related to a customized medical protocol comprises one or more medical questionnaires (col. 18, lines 6-17 of Douglas).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(E) Referring to claim 42, Douglas discloses wherein the information related to a customized medical protocol is converted from the customized medical protocol (col. 2, lines 40-66 of Douglas).

(F) Referring to claim 43, Douglas discloses wherein the information related to a customized medical protocol is converted by a corresponding medical monitoring device (col. 5, lines 28-64 of Douglas).

(G) Referring to claim 44, Douglas discloses wherein the information related to a customized medical protocol is converted by a device located remotely from a corresponding medical monitoring device that receives the information (abstract and Fig. 1 of Douglas).

(H) Referring to claim 45, Douglas discloses wherein the one or patients have at least one common characteristic determined based on the data received from the corresponding one or more medical monitoring devices (col. 7, lines 23-37 of Douglas).

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(I) Referring to claim 46, Douglas discloses wherein the common characteristic relates to demographics (col. 7, lines 23-28 of Douglas; the Examiner interprets "age" to be a form of "demographic").

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(J) Referring to claim 47, Douglas discloses wherein each of the medical monitoring devices is associated with a corresponding patient and is used to monitor the corresponding patient based on a medical protocol (col. 15, lines 51-58 of Douglas).

(K) Referring to claim 48, Douglas discloses wherein the medical monitoring device associated with a corresponding patient is configured for performing, based on a medical protocol, posing a questionnaire and gathering a response thereof (col. 18, lines 6-17 of Douglas).

Insofar as the claim recites "at least one of," it is immaterial whether or not the other elements are also disclosed.

(L) Referring to claim 49, Douglas discloses wherein the step of customizing comprises:

customizing a medical protocol related to a patient based on data received from a medical monitoring device associated with the patient (col. 2, lines 30-47 of Douglas);

determining one or more characteristics of the patient (col. 7, lines 24-37 of Douglas);

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identifying one or more different patients who possess the one or more characteristics (col. 7, lines 24-37 of Douglas); and

customizing one or more medical protocols related to the one or more different patients (col. 7, lines 24-43 of Douglas).

(M) Referring to claim 74, Douglas discloses a machine-implemented method for automatically customizing medical protocols, comprising the steps of (col. 2, lines 30-47 of Douglas):

receiving data from a medical monitoring device associated with a patient (Fig. 1, col. 2, lines 30-47, and col. 5, lines 27-33 of Douglas);

identifying one or more other patients who have characteristics common to the patient (col. 7, lines 23-37 of Douglas);

retrieving information associated with the one or more patients (col. 7, lines 23-37 of Douglas);

customizing medical protocols associated with the patient and the one or more other patients based on the received data and the retrieved information to derive customized medical protocols for the patient and the one or more other patients (col. 7, lines 23-44 of Douglas);

transmitting the customized medical protocols and/or information associated therewith to medical monitoring devices associated with the patient and the one or more other patients (Fig. 1 and col. 5, lines 27-33 of Douglas).

(N) Referring to claim 75, Douglas discloses a system for customizing medical protocol, comprising (col. 2, lines 30-47 of Douglas):

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receiving means configured for receiving data relating to one or more patients (col. 7, lines 23-37 of Douglas);

customizing means configured for automatically customizing one or more medical protocols based on the received data to derive one or more customized medical protocols (col. 7, lines 23-44 of Douglas); and

transmission means configured for transmitting the one or more customized medical protocols and/or information associated therewith to one or more medical monitoring devices associated with the one or more patients (Fig. 1 and col. 5, lines 27-33 of Douglas).

(O) System claim 80 repeats the subject matter of claim 74 as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Douglas in the above rejection of claim 74, it is readily apparent that the Douglas reference includes a system to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claim 74 and incorporated herein.

(P) Referring to claims 83, Douglas discloses wherein the customized medical protocols include a medication protocol customized for each patient (col. 2, lines 40-47 and col. 7, lines 15-21 & 28-31 of Douglas).

(Q) Claims 84-87 repeat substantially the same limitations as claim 83 and are rejected for the same reasons given above.

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al. (6,039,688).

(A) Referring to claim 81, Douglas discloses a method for customizing a medical protocol of a patient, comprising the step of (col. 2, lines 30-47 of Douglas):

implementing one or more medical monitoring devices to (Fig. 1 of Douglas):

provide medical questionnaires to one or more patients (col. 18, lines 6-17 of Douglas),

receive from the patient answers to one or more questions from the questionnaire (col. 18, lines 6-17 of Douglas), and

based upon the answers to the one or more of the questions by an individual patient, trigger an event conveying information to the individual patient (col. 7, lines 15-44 and col. 18, lines 38-62 of Douglas).

Douglas does not expressly disclose *selecting a specific questionnaire* to provide to the patient based on one or more shared characteristics of the patients.

However, Douglas does disclose selecting a program for the patient based on one or more shared characteristics of the patients (col. 7, lines 25-44 and Fig.

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6 of Douglas). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Douglas to include a specific questionnaire with the motivation of eliciting information that would provide a more accurate analysis.

(B) Referring to claim 82, Douglas discloses wherein the event includes providing a recommendation to the patient to carry out one or more behaviors related to managing their health (col. 18, lines 42-54 of Douglas).

Insofar as the claim recites "one or more of," it is immaterial whether or not the other elements are also disclosed.

Response to Arguments

7. Applicant's arguments filed 5/3/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 5/3/07.

(1) Applicant argues that no medication protocols are patient customized in Douglas. Douglas has nothing to do with medicinal practice.

(A) As per the first argument, the Examiner respectfully submits that Douglas teaches at col. 2, lines 40-47 the modification of the program to customize it for the patient. Douglas discloses that the patient's medications are taken into account (see col. 7, lines 28-31 of Douglas). In addition, note Fig. 7 (of Douglas) which clearly shows medications that are part of an individual's plan.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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In

6-27-07

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